

disease factors and cardiovascular therapy. Page 14 of the specification illustrates the use of the patient personal data and particle percentage distribution data.

Considering 954 patient samples (458 cases and 496 controls), age was a very significant predictor of CVD. Cases are significantly older than controls (60 vs. 52 years of age). After adjusting for the age difference, none of the risk factors are significantly different between the cases and controls. Thus, using the 954 patients, all of the differences in risk factors that exist between cases and controls are due to age, not disease status. All of these patients are high risk and the younger patients have not yet shown clinical manifestation of cardiovascular disease.

Using a subset of age matched cases (N=173, means 60 yr.) and controls (N=173, means 59 yr.) between 54 and 66 years of age, the cases had significantly:

Higher homocysteine (9.7 vs. 8.7,  $P<0.01$ ), and

Lower TC (179 vs. 201,  $p<0.0001$ ), LDLC (107 vs. 121,  $p<0.001$ ), triglyceride (140 vs. 163,  $p<0.05$ ), apoA1 (112 vs. 123,  $p<0.01$ ) apoB (85 vs. 96,  $p<0.001$ ), and TC/HDL2b (14.8 vs. 20.2,  $p<0.05$ ). These data indicate that the cases are more aggressively treated with medications than the controls.

Using a subset of age-matched cases (N=146, mean 55 yr.) and controls (N=93, mean 55 yr.) between 44 and 66 years of age without hyperlipidemia, the cases had:

Higher HDL3b (19.9 vs. 17.9,  $p<0.05$ ), HDL3 (58.8 vs. 55.7,  $p=0.08$ ) and LDLII+IV/HDL2+3 (0.40 vs. 0.38,  $p=0.11$ ), and

Lower TC (182 vs. 205,  $p<0.001$ ), LDLC (109 vs. 124,  $p<0.01$ ), HDLC (44 vs. LDL11A (16.8 vs. 18.2,  $p=0.09$ ), HDL2b (15.5 vs. 18.6,  $p<0.05$ ), and HDL2 (41.3 vs. 44.5,  $p=0.06$ ). These data again indicate that cases may be more aggressively treated with medications than the controls, even though they do not have hyperlipidemia. These data also indicate some important risk factors in the cases: a higher ratio of small LDL to HDL, small LDL size and lower HDL2b.

These data illustrate the value of the cardiovascular informatic knowledge base in deriving heretofore unrecognized relationships

between data, especially highly discriminating lipoprotein subfractions, in diagnosing risk factors which may govern the treatment of patients.

We note that this data is based on 948 patients because the LDL and HDL percentage distribution data can be stored. The LDL and HDL percentage distribution database is now based on over 100,000 patients and provides for insight on the relationship of LDL and HDL percentage distribution not previously known to the art, as well as, accuracy in risk assessment, diagnosis and treatment unavailable in the art.

The use of LDL and HDL percentage distribution data in the cardiovascular healthcare management system of the present invention provides cardiovascular risk factor assessment, diagnosis and management which is not obtainable in any prior art system. The comparison of patients LDL and HDL percentage distribution results to stored LDL and HDL percentage distribution data provides truly unobvious risk assessment, diagnosis and treatment of patients that is not contemplated or achievable by the prior art.

The cardiovascular management system is configured to present the data to remote physicians and provides for the physician interacting with the patient as shown in Figure 1. The prior art simply does not describe applicants cardiovascular healthcare system based on amounts of LDL and HDL subclass particles.

Allowance of claim 36 and claims 22-28 is earnestly solicited.

Respectfully submitted,

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Marked-up copy of Claims

21. (Cancel) A cardiovascular healthcare management system comprising:

(a) an infomediary site having databases that include percentage distribution of LDL and HDL subclass particles data derived from laboratory tests wherein the data is included.

(b) a data entry interface for receiving patient personal data and test results and storing the data and results in the infomediary site databases wherein the received test results includes patient percentage distribution of LDL and HDL subclass particles;

(c) a diagnostic engine for analyzing patient personal data and test results; wherein the diagnostic engine compares received patient percentage distribution LDL and HDL subclass particle data with other tests results to generate suggested treatment solutions to the physician.

22. The cardiovascular healthcare management system of claim [1] 36 further comprising a physician data access interface to allow physician access to the infomediary databases.

23. The cardiovascular healthcare management system of claim [22] 36 further comprising a communication system allowing the physician to communicate cardiovascular healthcare management information to the patient.

24. The cardiovascular healthcare management system of claim [21] 36 further comprising a cardiovascular knowledge base that stores information related to cardiovascular risk factors.

25. The cardiovascular healthcare management system of claim [21] 36 wherein the diagnostic engine includes algorithms for associating test results with possible treatments.

26. The cardiovascular healthcare management system of claim [21] 36 wherein the diagnostic engine includes algorithms for associating test results with possible diagnoses.

27. The cardiovascular healthcare management system of claim [21] 36 wherein the diagnostic engine includes algorithms for associating diagnosis information with possible treatment plans.

28. The cardiovascular healthcare management system of claim 27 wherein the treatment plans include personalized drugs, diet and exercise suggestions.

29. (Cancel) The cardiovascular healthcare management system of claim 22 wherein the physician dynamically selects parameters for treatment solutions based on patient test results trends.

30. (Cancel) The cardiovascular healthcare management system of claim 23, wherein the patient provides compliance data that is stored in the records for later review by the physician.

31. (Cancel) The cardiovascular healthcare management system of claim 29, further comprising a patient access interface whereby the patient accesses a cardiovascular treatment plan and views test results including trends over time.

32. (Cancel) The cardiovascular healthcare management system of claim 22, wherein the diagnostic engine analyzes patient test results and provides suggested diagnoses to the physician.

33. (Cancel) The cardiovascular healthcare management system of claim 22, wherein the diagnostic engine analyzes test result, patient data, diagnostic information and provides suggested treatment plans.

34. (Cancel) The cardiovascular healthcare management system of claim 22, wherein the diagnostic engine analyzes test results, patient data, diagnostic information and provides a baseline determination for ongoing therapy monitoring.

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35. (Cancel) A cardiovascular healthcare management system comprising:

(a) an infomediary site having databases for cardiovascular healthcare management which includes a database of test results for the percentage distribution of LDL and HDL subclass particles for cardiovascular patients;

(b) a data entry interface for receiving patient personal data and test results for percentage distribution of LDL and HDL subclass particles and storing the data and results in the infomediary site databases;

(c) a diagnostic engine for analyzing patient test results for percentage distribution of LDL and HDL subclass particles with the percentage distribution of LDL and HDL subclass particle database.

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36. (New) A cardiovascular healthcare management system comprising:

(a) an infomediary site having databases for cardiovascular healthcare management which includes a database of test results of amounts of LDL and HDL subclass particles for cardiovascular patients;

(b) a data entry interface for receiving patient personal data and test results for amounts of LDL and HDL subclass particles and storing the data and results in the infomediary site databases;

(c) a diagnostic engine for analyzing patient test results of amounts of LDL and HDL subclass particles with the LDL and HDL subclass particle database and relating such results to cardiovascular risk factors.